IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-CV-0191-MOC-DCK

KANAUTICA ZAYRE-BROWN, Plaintiff, v. THE NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY, et al., Defendants.	)	**AFFIDAVIT OF JOSEPH PENN, MD, IN SUPPORT OF DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

Professional Background

1. I am a psychiatrist based in Conroe, Texas. I am triple board-certified in forensic psychiatry, general psychiatry, and child and adolescent psychiatry. These board certifications are issued by the American Board of Psychiatry and Neurology, which is a member board of the American Board of Medical Specialties, the organization that grants board certification for psychiatrists and neurologists in the United States. I am fully licensed to practice medicine in Texas. I have been retained by Defendants in this matter to provide expert opinions.

2. I am currently the Director of Mental Health Services of the University of Texas Medical Branch (UTMB) Correctional Managed Care (CMC), which is a university-based correctional health care system. I have held this position since February 2008. In this capacity, I oversee the statewide provision of psychiatric, psychological, and mental health services to approximately 80% of adults (approximately 110,000 people) incarcerated in the Texas Department of Criminal Justice (TDCJ) which is the largest state prison system in the USA. This includes TDCJ's jails and state prisons. I also manage the child and adolescent psychiatric services of approximately 800 youths housed in the custody of the Texas Department of Juvenile Justice

(TJJD) and housed in various facilities across the state.

3. Over the past 30 years, I have devoted most of my professional time to the practice and teaching of general adult, child and adolescent, forensic, and correctional psychiatry. Since 1999, I have focused my clinical, administrative, and forensic work in correctional settings including adult and juvenile detention facilities, jails, and prisons, and non-correctional civil detention facilities.

4. Prior to relocating to Texas, I provided direct patient care and forensic psychiatry consultation in Rhode Island for approximately 15 years and in Connecticut for 1 year.

5. As the Director of Mental Health Services for the UTMB CMC, I oversee approximately 320 mental health staff including psychiatrists, psychologists, mental health managers and clinicians, case managers, psychiatric nurse practitioners (NP), psychiatric physician assistants (PA), and other qualified mental health professionals, as well as medical and physician assistant student trainees. I also directly supervise some psychiatric NPs and PAs and review and co-sign a percentage of their medical records. Additionally, I conduct peer reviews of psychiatrists and midlevel (NP and PA) psychiatric providers. I directly oversee all of the gender dysphoria specialists in our UTMB CMC system who provide direct patient care to transgender inmates with or without gender dysphoria. I also provide clinical supervision, approve or defer certain medications, support, prescribe, order, reorder, or adjust feminizing and masculinizing hormone medications and other psychotropic medications. Additionally, I provide other consultation and behavioral treatment recommendations to psychiatric and mental health, nursing, and medical treatment staff and to the custody leadership of the TDCJ. I also assist with direct patient care as needed, including by providing "on-call" after hours psychiatric coverage for both incarcerated TDCJ adults and TJJD youths statewide.

6. In addition to the above responsibilities and roles, during different periods of time, I served as the acting clinical director (i.e., the lead psychiatrist) of two dedicated inpatient psychiatric units, that house more than 500 adults. These units house TDCJ patients that are determined to be at imminent risk of significant self-injury or suicide, and/or have acute or serious mental health needs that cannot be managed at their assigned outpatient unit. Presently, I supervise the two current clinical directors that oversee the psychiatric and mental health care at these units. I am routinely involved in the referral, acceptance, admission, transfer, and discharge of patients within the state's dedicated inpatient psychiatric units. When needed, I also consult and oversee the evaluation and management of these inpatients, including transgender persons with or without gender dysphoria admitted to these inpatient psychiatric units, and of other particularly complicated patients across the TDCJ system. Additionally, I obtained hospital privileges at a local community hospital where several patients from our system were transferred.

7. I have achieved and maintained a specialized certification as a Certified Correctional Health Professional-Mental Health (CCHP-MH) since 2004. This certification is provided by the National Commission on Correctional Health Care (NCCHC) and requires passing a written national examination, demonstrating proficiency in national correctional health standards, annual attestation of continuing medical education credits, full medical licensure without restrictions, and must be recertified annually. The NCCHC provides health care accreditation of jails and short-term detention facilities, prisons, juvenile facilities, and opioid treatment programs for correctional facilities across the country. I have undergone specialized training to serve as a physician surveyor for the NCCHC and have surveyed several major metropolitan county jails and short-term detention facilities. I am also the past chair of the NCCHC accreditation committee and continue to serve as a committee member. Additionally, I have served

on several task force groups charged with revising certain NCCHC standards.

8. I remain current in the evaluation, diagnosis, and treatment of individuals within both correctional, forensic, and community settings. In particular, I remain knowledgeable about issues related to clinical psychiatry and systems of care in community settings, at both the state and national level, through my leadership work with organizations such the American Academy of Psychiatry and the Law (AAPL), the American Psychiatric Association (APA), the Texas Society of Psychiatric Physicians (TSPP), the American College of Psychiatrists (ACOP), and other medical and psychiatric organizations.

9. As such, I am familiar with mental health and psychiatry best practices, including in the evaluation and treatment of gender dysphoria and suicide prevention policies and practices in correctional, forensic, and community settings nationally. And I have published and presented in the areas of correctional mental health care and suicide prevention, and I have presented regarding the evaluation and management of incarcerated transgender individuals with and without gender dysphoria, at state, national, and international meetings.

10. I have also published extensively in scientific journals and other peer reviewed publications in the areas of correctional patient care, mental health needs of geriatric inmates, and other correctional mental health, recidivism, and continuity of care of incarcerated individuals with mental health and substance abuse, and suicide prevention topics.

11. I have been appointed to councils, committees, work groups, task forces and made numerous national and international contributions, within many organizations including but not limited to the APA, the American Academy of Child and Adolescent Psychiatry, and the AAPL. I served as an appointed member of the APA Council on Psychiatry and Law, which reviews law and psychiatry issues, and as past chair of the APA Council on Children, Adolescents and Their

Families.

12. I have presented nationally and internationally on correctional and non-correctional mental health care delivery and standards of care. Some recent examples of agencies that I have either consulted with or presented to, include: the Office of the California Attorney General; the Office of the Nevada Attorney General; the Sacramento County Commissioners and County Board of Supervisors; the Rhode Island Department of Corrections; the Vermont Department of Corrections. I also served as a consultant to the National Institute of Mental Health (NIMH) regarding detainees of U.S. Immigration and Customs Enforcement. And I have a pending invitation to present to the U.S. Department of Justice on suicide prevention in correctional settings. Other examples are listed in my CV.

13. I maintain clinical knowledge of the unique mental health and health care needs of incarcerated transgender individuals, with or without gender dysphoria. I completed specialized clinical training regarding the evaluation and treatment of this patient population under the supervision of Dr. Walter Meyer. Dr. Meyer, who is now retired, was a UTMB faculty psychiatrist and endocrinologist. Dr. Meyer is a respected international leader in transgender health care. Dr. Meyer was one of the members and lead authors on the World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) Volume 7 Revision Committee. World Professional Association for Transgender Health. (2012)[1].

14. I remain knowledgeable regarding the WPATH Standards of Care (SOC) and other relevant literature. I have presented nationally, and recently internationally, regarding the evaluation and diagnosis, clinical management, and treatment of transgender individuals with or without gender dysphoria within correctional settings.

[1] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* [7th Version] accessible at: https://www.wpath.org/publications/soc.

15. I have evaluated, diagnosed, and treated incarcerated TDCJ patients with gender dysphoria and have performed second opinion evaluations/consultations throughout Texas and other states. I oversaw the development and implementation of a specialized gender dysphoria referral and clinical program, which is a joint operation of the UTMB CMC, the TDCJ, and Texas Tech University. This program is used throughout the TDCJ system. I continue to oversee the program and maintain direct clinical involvement in the same. I have also overseen the systemwide development, revisions, and implementation of a disease management guideline for the evaluation and treatment of incarnated adults seeking evaluation and treatment for gender dysphoria. I have also provided input and assisted with revisions to the State of Texas's Correctional Managed Health Care Committee policy entitled Policy G-51.11 Correctional Managed Health Care Policy Manual, which concerns the treatment of incarcerated persons with intersex conditions and gender dysphoria. I have also served as a consultant to several state prison systems including Colorado, Kansas, New Jersey, and California regarding gender dysphoria diagnoses, evaluation and treatment programs, policies, and practices, and medical and surgical interventions for various state inmates.

16. I have served as an expert witness in both civil and criminal matters. In civil matters, I have been retained by and served as an expert for both plaintiffs and defendants. Likewise, in criminal matters, I have been by retained and served as an expert for both the prosecution and defendants. Additionally, I have served as a court-appointed expert in civil and criminal matters. As such, I have been qualified as an expert witness in various state and federal courts, in the fields of forensic, child and adolescent, and correctional psychiatry. I have provided expert opinions in several areas, including the standards of care in different types of correctional facilities and other settings, the use of psychotropic medications, psychic harm, PTSD, suicide,

suicide prevention, suicide risk assessment, seclusion and restraint, and other topics.

17. For a period of time between 2013 and 2014, I served as a correctional psychiatric consultant to the Special Master in the case captioned *Coleman v. Brown, Governor of California, et al*., Case No. CIV. S-90-520 LKK/DAD (PC) in the United States District Court for the Eastern District of California.

18. From 2017 to 2019, I served as a consultant to the State of California's Office of the Attorney General concerning several topics such as mental health staffing, telepsychiatry, and the improvement of health care delivery efficiency in the California Department of Corrections and Rehabilitation prison system. And effective this month, July 2022, I am again serving as a consultant regarding the use of telepsychiatry within correctional settings.

19. Additionally, since 1998, I have conducted numerous evaluations and site tours of various state prisons in Rhode Island, Vermont, Texas, California, and Arizona. I have also conducted evaluations and site tours of several county jails and juvenile detention facilities in Florida, and ICE facilities across various jurisdictions.

20. I am also familiar with different custody and housing levels, inmate movements for various activities, and other operational issues concerning the incarcerated population. Thus, I have a fundamental appreciation of the impact, interplay, and communication between correctional custody, nursing and medical staff and other staff, and mental health care delivery in the carceral setting. This is of particular relevance to providing care to transgendered inmates with or without gender dysphoria.

21. For a more detailed statement of my education and experience, see my *Curriculum Vitae* (CV) attached hereto as Exhibit A.

22. Due to my professional experience, as described above and in my CV, I am well

positioned to render opinions regarding the provision of psychiatric, mental health, and medical services in a correctional setting to transgender patients with or without gender dysphoria. And I am also well positioned to render opinions concerning the medical, psychiatric, mental health and other clinical indications for various courses of treatment aimed at addressing gender dysphoria, including surgical interventions; and the safety, effectiveness, associated risks, costs, and benefits of, and the alternatives to, such treatment options.

23. All conclusions and opinions stated herein are based upon my years of education, training, and professional experience, as well as my review of Plaintiff's medical and mental health records, her motion for preliminary injunctive relief, and supporting materials, which included a declaration signed by Randi C. Ettner, Ph.D. Additionally, all conclusions and opinions stated herein are stated to a reasonable degree of medical, psychiatric, and mental health certainty.

Policies Concerning Evaluation and Management of Transgender Patients in Correctional Settings

24. It is critical to note that there are currently no published national correctional standards or correctional health standards concerning the policies and/or protocols for the evaluation, treatment, or clinical management of transgender individuals with or without gender dysphoria in the carceral setting. Thus, organizations such as the American Correctional Association, the NCCHC, the American Psychiatric Association, and the American Psychological Association, and other medical and professional organizations, do not have specific clinical guidance for correctional systems regarding what constitutes minimum or best practices or standards of care for the evaluation and management of this population of incarcerated individuals.

25. That the only correctional health accrediting body in the US, the NCCHC, does not have any correctional health standards concerning this population, is significant. The NCCHC's origins date to the early 1970s, when an American Medical Association (AMA) study found

inadequate, disorganized health services, and a lack of national correctional health standards. In collaboration with other medical, legal, and other professional organizations, the AMA established a program to address the issue. In in 1983 this program became an independent, 501(c)(3) nonprofit organization—the NCCHC. The NCCHC is supported by major national organizations in the health, mental health, legal, and corrections fields, including the American Bar Association (ABA), the AMA, the American Nurses Association, the American Public Health Association, the National Association of Social Workers, and others. The NCCHC publishes national correctional health care standards, position statements, and provides educational conferences to guide correctional health professionals, administrators, and systems. Given the NCCHC's history, its work, its educational and clinical training mission, the multi-disciplinary input, and the support it receives, the fact that the NCCHC does not currently have any published guidance or correctional health care standards on this specific topic is significant because it indicates the tremendous lack of consensus in the correctional health care and administrative and custody staff community on this complicated topic.

26. The NCCHC does have a 2020 position statement entitled: "Transgender and Gender Diverse Health Care in Correctional Settings."[2] That position statement, which I assisted in revising and approving, addresses, at a high-level, the challenges in evaluating and managing the incarcerated transgender population. It is important to note that this new NCCHC position statement, like others, is a statement of an aspirational goal or ideal in the correctional field and thus does not in any way assert itself or represent itself to be a standard of care, definitive clinical expectations or mandates to the field. Nor is the position statement intended to stand on its own as a disease management guideline or clinical protocol, or as a consensus statement. Instead, it

[2] https://www.ncchc.org/transgender-and-gender-diverse-health-care-in-correctional-settings-2020

provides some general and non-specific "real world" practical guidance to correctional health and administrative and custody staff on issues to consider with this special population. Accordingly, these types of positions statements are of limited assistance in crafting definitive policy and procedures concerning the evaluation and management of transgender individuals with or without gender dysphoria in various correctional settings. This is especially true given the tremendous variability in size of facilities, clinical staffing and resources, and the varying and other numerous patient variables and population characteristics. Moreover, the NCCHC is explicitly clear that its existing standards and position statements do not define any medical or mental health or other health care "standard of care."

27. As such, correctional leaders with specialized knowledge and experience in correctional medicine, psychiatry and health care, and custody and operational leaders must work together and develop highly individualized practices, policies, and procedures without the benefit of any current national correctional standards. Also, in doing so, systems must avoid an overreliance on standards promulgated by national organizations who lack correctional experience or knowledge. The lack of any current national standards contributes to the numerous unique challenges faced by correctional systems when developing and implementing comprehensive care protocols for transgender persons with or without gender dysphoria.

28. When creating such health care protocols, disease management guidelines, and related policies, procedures, and practices, correctional agencies must develop their policies and procedures based on a variety of sources of information. These sources of information can include the existing WPATH recommendations, local medical and community practices, if available, recent legal cases (some of which have highly disparate rulings), and the one limited and highly generalized position statement of the NCCHC. Gathering, reviewing, and synthesizing this

information so that useful standards and protocols can be developed and implemented, which includes training various multidisciplinary health care and custody staff on these challenging topics across large and complex systems is no small feat.

29. The North Carolina Department of Public Safety ("the Department") has developed a policy and set of procedures concerning the evaluation and management of the transgender population. I have reviewed the Department's policy. It, like many other correctional systems, relies on a multidisciplinary review process. It is my understanding that the multidisciplinary team that reviews various requests by incarcerated transgender patients for certain medical, mental health, and surgical inventions, includes individuals with decades of experience in custody/corrections, medical care, psychiatry, behavioral health care, and other disciplines.

30. An attribute of the Department's approach in its policy that is of particular importance, is that the policy is fluid and evolving. This results in an approach that can more easily be refined and updated as needed.

31. Given the complexity of addressing certain needs of some of the transgender incarcerated population, the Department's policy rightly provides for a case-by-case review and evaluation of various requests for interventions. This approach allows for the Department to assess various aspects implicated by certain requests and to do so in a way that accounts for the reality of providing health care in the correctional setting. In doing so, the Department's individualized approach acknowledges and appreciates that every incarcerated individual is different and thus requires an individualized evaluation and treatment plan approach for each person and that correctional health care requires numerous additional unique considerations. This is critical because gender dysphoria falls along a spectrum—so does the array of various and possibly effective treatment options. Thus, there can be no blanket solutions or approaches. Additionally,

the need for case-by-case considerations and fluidity in responding to changes in circumstances is particularly important in the correctional setting because of the unique factors attendant therein which are not present in the community.

32. Based on my review of the Department's policy, my approximately 30 years of correctional health care experience, and my knowledge and training concerning transgender health care in the carceral setting, it is my opinion that the Department's policy comports with or exceeds what I would consider to be an acceptable standard for a comprehensive set of health care protocols for transgender patients, with or without gender dysphoria, in a correctional system. Indeed, the Department's policy and procedures are equivalent to those of other state prison systems, including some of the larger systems in the country.

33. Further, it is my opinion that the Department's policy is necessary, integral, and instrumental to ensuring the timely provision of quality psychiatric, mental health, and other medical care to transgender patients, with or without gender dysphoria. Additionally, it is my opinion that the Department's practices, policies, procedures, referral, diagnostic/evaluation, and gender dysphoria treatment approaches and practices comport with evidence-based practices.

34. Therefore, it is my opinion that the Department's policy provides for the requisite access to care and continuity of care to transgendered individuals housed in North Carolina state prisons.

Unique Considerations in the Correctional Setting

35. That the correctional setting is different than the community is obvious. However, there are a host of considerations regarding the delivery of health care, in general, and in particular the management of transgender health care, in the correctional setting which are not so obvious.

36. Additionally, in the correctional setting, unique issues must be considered that are

simply not present in the community. Or issues that must be considered in community, must be considered in the unique context of the correctional setting.

37. For example, in the community, a person's legal or criminal history is not factored into an analysis of whether to proceed with a particular intervention, or even whether certain decisions are even considered interventions. This is not the same in the correctional context. In the correctional setting, a person typically has no control over where they are housed or with whom or the number and location of cellmates. But a person may request a certain type of housing assignment. A transgender person may request a particular housing assignment as an intervention aimed at ameliorating one's gender dysphoria. In such a scenario, a person's past legal or criminal history, mental health and medical status and clinical stability, disciplinary history, which may include a history of physical assaults on peers or staff or both, or history of sexual offending in the community or while incarcerated, security threat group/gang affiliations, and other variables must be taken into account for safety and security reasons. To illustrate, a transgender female inmate with a history of sexual violence against females who now requests transfer from a male facility to a female facility by an individual with a history of sexual violence or abuse will warrant further consideration than the same request by someone without such a history. These considerations are not just theoretical. These considerations have serious implications for other inmates and staff, as they may pose a risk of disruption to the unit safety, rehabilitation efforts, treatment efforts and programming, the overall unit milieu, and sense of safety and risks of physical and sexual assaults and intimidation and coercion to other potentially vulnerable inmates in particular. There are news reports of at least one recent instance[3] of a transgendered female, that still had male genitalia,

[3] https://www.nj.com/news/2022/04/two-women-at-nj-prison-are-pregnant-after-consensual-sex-between-inmates-doc-says.html; https://news.yahoo.com/nj-transgender-woman-transferred-women-134955783.html?guccounter=1.

impregnating female inmates in a female prison unit in New Jersey.

38. Similarly, there is extensive literature[4] indicating that incarcerated females have extensive trauma and victimization histories, including adverse childhood experiences and past domestic violence, emotional, physical, and sexual abuse, exploitation, and other traumas. Thus, placing a transgendered female who has masculine secondary characteristics (e.g., body shape and stature, broad shoulders, masculine voice, etc.) in a female prison unit might result in triggering/re-experiencing of fear, avoidance, other trauma recollection, PTSD experiences, flashbacks, and other indications of clinical deterioration, all of which can result in various forms of self-harm, and other morbidity and mortality of the females already housed in that unit.

39. While the above examples concern housing considerations, which I understand are not at issue in this phase of the litigation, custody, housing and classification determinations and other custody related considerations, that are unique to the correctional setting, must also be seriously considered with regard to any other interventions, including medical (hormonal treatments) and/or surgical interventions. Surgical considerations include, but are not limited to, the psychiatric/mental health stability of the patient, the availability of qualified in-state surgeons with particular knowledge and expertise in performing various surgeries for transgendered individuals and who are comfortable and are willing to provide surgery to incarcerated individuals, rates of patient acceptance and satisfaction with the particular proposed surgeon or surgical

[4] Stanton AE, Rose SJ. The Mental Health of Mothers Currently and Formerly Incarcerated in Jails and Prisons: An Integrative Review on Mental Health, Mental Health Treatment, and Traumatic Experiences. J Forensic Nurs. 2020 Oct/Dec;16(4):224-231. Doi: 10.1097/JFN.0000000000000302. PMID: 32947439.

Nowotny KM, Belknap J, Lynch S, DeHart D. Risk profile and treatment needs of women in jail with co-occurring serious mental illness and substance use disorders. Women Health. 2014;54(8):781-95. Doi: 10.1080/03630242.2014.932892. PMID: 25204664; PMCID: PMC4224671.

Lewis C. Treating incarcerated women: gender matters. Psychiatr Clin North Am. 2006 Sep;29(3):773-89. Doi: 10.1016/j.psc.2006.04.013. PMID: 16904511.

practice, effectiveness of alternative non-surgical interventions, short and long term clinical outcomes, risks of anesthesia and surgery and post-surgical complications, potential benefits versus the patient's perception of harm from postponing the procedure (until it can be performed in the community), pre-operative procedures, post-operative care, costs of the procedures, attainment of fully informed consent (e.g., the patient's ability to weigh the various risks, benefits and alternatives and provide truly voluntary informed consent), and more. All of these factors warrant consideration regardless of the proposed surgical intervention at issue. And this is especially true with regard to the provision of gender-affirming surgery, including the vulvoplasty requested by the Plaintiff, due to the irreversible and permanent nature of the surgical removal of the patient's penis, and the associated risks and potential post-surgical complications involved

40. It is my understanding that a vulvoplasty is a highly specialized urologic surgical procedure that is not performed by a great number of surgeons. Thus, I would anticipate a longer wait time for this procedure than with other less specialized and more routine non-genital surgeries. In the correctional setting, the availability of qualified and willing surgical professionals to perform such a given procedure, and in particular to an incarcerated individual who will be returning to a state prison setting post-operatively opposed to the community is critical because the pre-operative testing, actual surgical procedure, and post operative follow-up appointments must be scheduled to account for a variety of correctional and custody related issues. These include planning and coordination of transportation to and from the prison to the surgeon's office or community or academic center hospital or clinics for pre-operative evaluations, blood work and EKG and other pre-operative tests, bowel preparation and fasting must be coordinated, custody staff escorts and supervision at all times (e.g., due to the risks of escape or taking staff hostage or other safety issues) and whether the surgeon, clinic, practice or hospital has trepidation regarding

these issues and custody staff present in the waiting room, patient room, and the like. Similarly, planning for the procedure must allow sufficient time for post-operative follow-up with the surgeon to monitor wound healing. Importantly, considerations for planning and coordinating surgery must also consider whether the surgical recovery and other post-operative timetables falls within an incarcerated person's projected release date. An additional major public health variable facing correctional patient populations is the issue of communicable diseases such as COVID-19, tuberculosis, MRSA (methicillin resistant staph aureus) skin infections, candida (fungal infections) and transmission and other infectious disease risks, transmission, infections, status and the ability to safely transport the inmate patient to/from a hospital setting for appointments, the planned surgery, and post-surgical interventions (should there be complications) during the current COVID pandemic and in particular due to recent variants and correctional and community infections and re-infections. Dr. Ettner's declaration does not appear to meaningfully address these numerous important issues or considerations.

41. Consideration of the rate of patient satisfaction with a particular surgeon and/or of a given surgical intervention is also extremely important. This is especially true when considering an irreversible and complicated procedure, such as the type requested by Plaintiff. This consideration is even more critical in light of the Plaintiff's expressed desire to undergo additional surgery in the same area. Some of the Plaintiff's records indicate that she initially wanted a vaginoplasty but opted to request a vulvoplasty due to a sense of expediency and post-operative concerns. However, her records also indicate that even after verbally expressing a preference on the day of the scheduled clinic appointment to the surgical staffer for a vulvoplasty, that the Plaintiff expressed a desire to pursue the vaginoplasty at a later date after first undergoing the vulvoplasty. Thus, in this case, not only must patient satisfaction concerning a vulvoplasty be

considered, so too must satisfaction and anticipated compliance and follow through in pursuing a vulvoplasty as the first phase to be followed by a vaginoplasty as a second phase. Moreover, any patient satisfaction's regarding any reconstructive surgical procedure is highly variable, especially when serial (back-to-back similar) surgeries are required. Additionally, any repeat surgery poses additional risks of adhesions, scarring, decreased range of motion/movement, and further surgical complications. Dr. Ettner's declaration does not appear to meaningfully address these considerations.

42. A correctional system must also consider its ability to address pre and post-operative issues described above, and potential short and long-term continuity of care and placement issues which may arise following any type of surgery. This would include an assessment of the ability to ensure an appropriate level and type of care immediately following surgery. Issues such as location of recovery, staffing levels (medical and custody supervision), and transportation will factor into this near-term analysis. A correctional system will also need to consider any potential short and long-term implications of any proposed surgical intervention. This consideration may turn on issues such as whether a more permanent housing arrangement is warranted and that determination involves factors such as post-surgical observation in a medical infirmary during immediate post-surgical recovery period, whether there will be an indwelling catheter, IV or oral antibiotics, pain medication administration, wound care, or other interventions, whether and which types of follow-up surgeries (or other procedures) are likely, and whether and how an incarcerated post-surgical patient's activities of daily living (e.g. walking from assigned housing cell to day room, walking to the cafeteria, work assignments, day room and recreational activities, shower and bathroom) may be impacted, as this may have implications for other services (medical or otherwise) provided by the prison. Also, a system must assess the potential

complications and risks associated with the given surgical intervention, as this assessment may be critical in the broader continuity of care and placement considerations. I understand that this patient has requested a specific gender affirming surgery, a vulvoplasty, which is a particularly delicate and highly complex surgery. The same is true with other gender affirming surgeries like vaginoplasty, penectomy, orchiectomy, and others. Indeed, Current Urology Reports recently noted that in the largest single-site study performed by an experienced surgeon an estimated incidence of 28.7% complication rate attributed to male to female gender affirming surgery was reported.[5] Thus, there appears to be a moderately high rate of complications, regardless whether the patient pursues vaginoplasty or a vulvoplasty followed by a vaginoplasty. These complications may include things like: rectoneovaginal fistulas, bleeding from the well-vascularized spongiosum tissue of the urethra, urethral meatus stricture, vaginal stenosis, hair in the vagina, pain with dilation, formation of granulation tissue, vaginal tear, and issues with cosmesis. Additionally, many patients seek re-operation to include a revision labiaplasty, with greater than half of the cases performed for cosmetic reasons. When fistulas do occur, small ones can be managed conservatively with bowel rest. However, more complicated cases may require surgical excision and possible intestinal diversion. Also necrosis and loss of the neovaginal pouch will require a substitution with virgin tissue from another well vascularized flap, most commonly the ileum or the sigmoid. Vaginal stenosis occurs with a frequency of about 14% but surgical correction is required in only about 41% of those cases. Dr. Ettner's declaration does not appear to meaningfully address these considerations.

43. Assessing the effectiveness of alternative interventions is also critical, particularly complex surgical intervention. In this case, it is my understanding that the Plaintiff has been

[5] Shu Pan & Stanton C. Honig. "Gender-Affirming Surgery: Current Concepts," Current Urology Reports (2018) 19:62 https://doi.org/10.1007/s11934-018-0809-9

transferred to a female facility, has been on feminizing estrogen therapy, has been receiving individual psychotherapy (e.g., talk therapy), and has been on multiple medications in an effort to address her gender dysphoria. Yet, Dr. Ettner's declaration does not contain a robust examination of the effectiveness of those non-surgical and well accepted interventions for an individual with DSM-5-TR gender dysphoria. Before approving a request for a vulvoplasty, or any other irreversible gender-affirming surgery, a correctional system would need to fully evaluate whether all other viable risks, benefits, and other alternatives have been considered, and to what extent they have been effective, and if not some inquiry into why. This consideration would also involve evaluating an individual's active participation and compliance with offered medical and mental health treatment modalities that are available and offered.

44. Additionally, correctional systems must assess the costs of approving various medical and other health care interventions for any disease state. These will include common chronic diseases, such as hypertension, diabetes, asthma, lower back pain, arthritis, chronic pain, headaches, and elevated cholesterol, various infectious diseases, such as tuberculosis, HIV, Hepatitis B and C, serious mental illness, such as schizophrenia and other psychotic disorders, and bipolar disorder, impulse control disorders, personality disorders, and more common mental disorders such as depressive and anxiety disorders, and more costly disease states, such as hemodialysis for end stage kidney disease, bone marrow or solid organ transplants, chemotherapy, or immunologic treatment for cancer and malignancies or clotting agents for blood clotting dyscrasias. Because correctional agencies are publicly funded, these entities must consider the financial implications associated with approving certain treatment modalities from the perspective of the government leaders such as legislature, public policy leaders, and taxpayers. And because these agencies provide care for thousands of patients, many with multiple disease states, high

comorbidity, past high risk-taking behaviors, and certain other considerations, like patient compliance and access to specialty care, particularly when approving interventions for the first time, must be considered at the system-level and not just at the individual level. Thus, a correctional agency, like the Department, must utilize its dollars in a way that allows it to provide for the health care needs of all persons in its care and custody most efficiently and fairly.

45. For example, there are new agents of long-acting injectable antipsychotic medications which may benefit some patients with chronic and treatment resistant psychotic disorders who refuse to take oral antipsychotic medications. However, these new agents are extremely expensive when compared to tried and true older and much less expensive medications with a long track record of clinical efficacy and safety in clinical practice. Given the costs associated with procuring and administering these new agents a system would undoubtedly undertake a cost-benefit analysis, medication use evaluation, and clinical rationale/justification of the proposed use of the new agent. Thus, considering costs is reasonable, and indeed prudent, when determining whether to proceed with a particular course of treatment in a correctional system which provides health care to thousands, and does so with public funds. Dr. Ettner's declaration does not appear to meaningfully address these considerations.

46. An assessment of whether the patient has truly provided fully informed consent is also critical. Prisons are inherently coercive settings, thus, in the correctional setting extra care must be taken to determine, as best as possible, that the patient understands the risks, benefits, and alternatives to a given procedure. Many of the considerations referenced above factor into this calculation. Informed consent, especially in the context of a surgery undertaken to address a condition, should include an assessment of the patient's expectations about their understanding of the potential ameliorative effect of the procedure. If the purpose of undergoing the surgery is to

reduce a patient's dysphoria, an exploration of why and how the patient believes this will occur is crucial. In the Plaintiff's records, she indicates a variety of factors that appear to affect her dysphoria, including the attitudes of other prisoners and complications stemming from the strict sex-based housing assignments. Surgical interventions will have no bearing on these factors. Thus, a discussion with the Plaintiff about her expectation of how and why she believes the surgery will ameliorate her dysphoria is critical. It does not appear that Dr. Ettner addressed this in her declaration, which makes her assertion that the vulvoplasty would be curative particularly specious.

47. Given the plethora of considerations in assessing the appropriateness of any given surgical intervention in the correctional setting, the potential impact of postponing the procedure until it can be performed in the community must also be evaluated. I understand that the Plaintiff's projected release date is November 2, 2024.[6] At that time, the Plaintiff will be able to pursue whichever surgical intervention she desires. Surgery in the community typically carries numerous interpersonal and social benefits over surgery in the correctional setting. In the community, a patient can recover from a surgery in the comfortability of their home and with the therapeutic aid, support, attention, and care from loved ones. Moreover, in the community a patient typically has some choice in the selection of a surgeon, which in the context of gender-affirming surgery, is something I understand may be fundamental to patient satisfaction with the outcome. Thus, such benefits must be balanced against the potential hardship of waiting to undergo the surgery in the community. Dr. Ettner does not appear to thoroughly address this consideration either.

The Department's Evaluation of Plaintiff's Request for a Vulvoplasty

48. Because of the lack of a sufficient body of "gold standard" controlled, high quality,

[6] This information is publicly available at https://www.ncdps.gov/dps-services/crime-data/offender-search.

and empirical research at the intersection of transgender health care and corrections, and the absence of any national correctional health care standards posing specific "do's and dont's" or other specific clinical recommendations regarding evaluation and treatment approaches and practice guidelines for incarcerated transgender individuals with gender dysphoria from organizations like the NCCHC, some clinicians, expert witnesses, and others rely exclusively on the guidance promulgated in the WPATH's SOC. Overly or solely relying on the WPATH standards for evaluating the appropriateness of an intervention in the correctional setting has three distinct faults.

49. First, the WPATH standards do not provide any meaningful correctional specific guidance. While the authors assert that the SOC standards should apply in the correctional setting just as in the community, they do so based on very limited data and without accounting for the realities of correctional medicine. I understand that the authors of the SOC were comprised of a multidisciplinary team that included endocrinologists, psychiatrists, psychologists, and other medical professionals. However, it is my understanding that none of these individuals had any correctional clinical or administrative experience. Perhaps not surprisingly then, WPATH does not appear to appreciate or recognize the various nuances, challenges, and differences inherent delivering health care in the correctional setting, some of which are outlined above. To date[7], the WPATH has not provided any meaningful clinical or administrative guidance concerning application of their standards in the correctional setting. Thus, the WPATH SOCs have limited value in providing definitive clinical guidance and management and application to correctional medical and mental health staff who evaluate and manage the care of transgender persons with or

[7] I have reviewed a draft version of the pending WPATH "SOC" Volume 8 (which is currently in revision for future publication and dissemination). This document similarly lacks any guidance or cautions regarding generalizability and applicability within correctional settings

without gender dysphoria in the correctional context. Indeed, it is my understanding that the WPATH guidance was primarily intended to guide the evaluation and treatment of individuals within community settings.

50. Second, the authors of the SOC, however well intentioned, appear to direct their efforts in furtherance of advancing transgender health care advocacy. This raises some concerns that WPATH, as a member organization as opposed to an accreditation entity or a purely educational organization, may have an advocacy orientation that detracts from the academic and research rigor of a more solely evidence-based/research organization. While advocacy for this special patient population is certainly admirable, consideration of how that advocacy may influence the organization's publications, especially when promulgated as standards of care, is reasonable. This focus on advocacy corresponds extremely well with the primary goal as stated on page 7 of the 7th version of the SOC: "the overall goal of the SOC is to provide clinical guidance for health professionals to assist transsexual, transgender, and gender-nonconforming people with safe and effective pathways to achieving lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment." While undoubtedly a noble goal, striving for such an objective of self-fulfillment does not, in and of itself, provide for a medical or surgical or mental health/psychiatric standard of care that is useful in the correctional setting.

51. Third, applying the WPATH's SOC as true standards of care for the incarcerated patient population is highly problematic for multiple reasons.

52. As an initial matter, I am unaware of any other medical or psychiatric organization that has any organizational medical publication titled "Standards of Care (SOC)." I am familiar with the writing of position statements, practice guidelines, and practice parameters, which

requires the writer to identify for the reader the level of importance and or certainty possible for each specific recommendation. As an example, I was the lead author of a practice parameter[8] for the assessment and treatment of youth in juvenile detention and correctional facilities. In this practice parameter, we provided specific categories indicating the degree of importance or certainty of each recommendation. These categories were "Minimal Standards" which referred to practice recommendations that were based on substantial empirical evidence (such as well-controlled, double-blind trials) or overwhelming clinical consensus. Minimal Standards practices are expected to apply more than 95% of the time. "Clinical Guidelines" referred to recommendations that were based on some empirical evidence and/or strong clinical guidelines. Clinical Guidelines are expected to apply approximately 75% of the time. "Options" referred to practices that were acceptable, but not required, likely because they lack sufficient empirical evidence to warrant recommendation at a higher level of certainty. Lastly, "Not Endorsed" referred to practices that are known to be ineffective or contraindicated. These categories allowed practitioners to refer to a particular recommendation with a clearly articulated evidence base for use and consideration. The WPATH's SOC simply do not contain the requisite level of clarity regarding the evidence base to guide the field.

53. Also, an over or exclusive reliance on the WPATH's SOC in the correctional setting runs headlong into the lack of any research in the correctional setting. I conducted a recent literature review to determine if there is any literature regarding surgical intervention as a treatment for gender dysphoria in the correctional setting—I found none. In conducting this review, I used the Pub Med Search service, and input the following search terms: "Gender-affirming surgery

[8] Penn JV, Thomas CR. AACAP Work Group on Quality Issues. Practice Parameter for the Assessment and Treatment of Youth in Juvenile Detention and Correctional Facilities. J Am Acad Child Adolesc Psychiatry 2005; 10:1085-1098

(GAS)" **AND "**Corrections" "Correctional Settings" "Incarcerated Patients" "Incarcerated Individuals".

54. Finding no literature in the correctional context, I reviewed the available literature concerning the effectiveness of surgery as an intervention in the community. Before turning to the conclusions of those studies, a few points are worth making. First, none of the available literature involves empirical studies done in the United States. There are some survey studies and re-analyses of survey studies, but I was unable to locate original studies that included clinical interviews with pre-surgical baseline and post-surgical follow-up assessments or that employed any validated screening or follow-up measures or testing. Second, none of the studies are longitudinal, which would be helpful in determining the long-term effectiveness of surgical intervention. Third, none of these studies are performed under the ideal models, (i.e., a control group, case matched or case control study design). Thus, relying on such surveys and re-analyses of survey studies and extrapolating results to the carceral setting is not a sound methodology.

55. Turning to the conclusions of these studies, which attempt to analyze the effectiveness of gender affirming surgery, some studies suggest that surgical intervention may be effective. For example, Richard Bränström, Ph.D., John E. Pachankis, Ph.D, published a commonly cited Swedish study that reported a reduction in mental health treatment utilization: "Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study." The conclusions therein included that, the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them.

56. However, after the article "Reduction in Mental Health Treatment Utilization

Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study" by Richard Bränström, Ph.D., and John E. Pachankis, Ph.D. (doi: 10.1176/appi.ajp.2019.19010080), was published online on October 4, 2019, some letters containing questions on the statistical methodology employed in the study led the *Journal* to seek statistical consultations. The results of these consultations were presented to the study authors, who concurred with many of the points raised. Upon request, the authors reanalyzed the data to compare outcomes between individuals diagnosed with gender incongruence who had received gender-affirming surgical treatments and those diagnosed with gender incongruence who had not. While this comparison was performed retrospectively and was not part of the original research question, given that several other factors may differ between the groups, the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts in that comparison.

57. Given that the original study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that "the longitudinal association between gender-affirming surgery and lower use of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them" is too strong. Finally, although the percentage of individuals with a gender incongruence diagnosis who had received gender-affirming surgical treatments during the follow-up period is correctly reported in a table (37.9%), the text incorrectly refers to this percentage as 48%. (emphasis added). The article was reposted on August 1, 2020, correcting this percentage and including an addendum referencing the post-publication discussion captured in the Letters to the Editor section of the August 2020 issue of the Journal.[9]

[9] Kalin NH: "Reassessing mental health treatment utilization reduction in transgender individuals after gender-affirming surgeries: a comment by the editor on the process (letter)." Am J Psychiatry 2020; 177:765.

58. Other controlled studies either suggest that surgery may not be particularly effective or at least call the opposite conclusion into question. In the published Swedish study, Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, Cecilia Dhejne et al., noted in the Context section: "The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment." The following Results were noted: "The overall mortality for sex-reassigned persons was higher during follow-up than for controls of the same birth sex, particularly death from suicide. Sex-reassigned persons also had an increased risk for suicide attempts and psychiatric inpatient care. Comparisons with controls matched on reassigned sex yielded similar results. Female-to-males, but not male-to-females, had a higher risk for criminal convictions than their respective birth sex controls." The authors wrote the following in their Conclusions: "Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population. Our findings suggest that sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group."

59. Accordingly, my literature review indicates that there are studies[10] that reach highly conflicting conclusions on the topic of the long-term effectiveness and efficacy of gender affirming surgery. Moreover, there are no published studies that clearly demonstrate a cause and effect definitive "cure" or total alleviation of gender dysphoria symptoms or distress subsequent to gender affirming surgery.

[10] The studies noted herein are not intended to be exhaustive but only representative. There are multiple other studies on the topic that reach conflicting conclusions.

60. Given the lack of studies on this topic in the correctional setting, the conflicting conclusions of existing research, and the limitations of the same, it is my professional opinion that to date, there is no medical consensus that substantial evidence exists supporting the use, acceptance, satisfaction, validity, reliability, and clinical outcomes of gender affirming surgery within the community or in the correctional populations in the United States.

Plaintiff's Formulation of Medical Necessity is Flawed

61. The Plaintiff and her expert, Randi Ettner, Ph.D., take the position that the requested vulvoplasty is "medically necessary." This position appears to turn on a formulation of the phrase "medical necessity" which labels an intervention necessary so long as it has the potential to provide some therapeutic benefit. Such a formulation is not particularly helpful, accurate, or practical in the correctional setting. This is especially true when determining the appropriateness of a surgical intervention to treat to gender dysphoria.

62. This formulation of "medical necessity" is particularly problematic because there are no objective indicators or metrics of the progress in treating gender dysphoria. This is unlike other types of medical conditions, such as high blood pressure, diabetes, or glaucoma, which can be assessed and monitored by examinations, other testing, or lab testing. There is no equivalent for measuring progress of a person's gender dysphoria. Rather, progress is solely based on self-reports and subjective life experience, and as such can be highly variable and unpredictable. For instance, some experience rapid effects from feminizing or masculinizing hormone therapy and may report feeling lower levels of dysphoria, while others may feel dissatisfied and continue to report higher levels of dysphoria.

63. Under the formulation of the phrase "medically necessary" as used by the Plaintiff and her expert, an intervention which may provide some benefit vis-à-vis a patient's gender

dysphoria becomes medically necessary. However, that same logic would make a host of other interventions "medically necessary" to treat other conditions. For example, a patient with a perception of a large nose, skin wrinkles or sagging, or other distress or discomfort due to perceived facial or body features may derive a benefit from procedures targeting that body feature, such as a rhinoplasty, botox, or facelifts. Thus, under Plaintiff's logic these procedures would be "medically necessary" because they may well benefit the patient by alleviating, to some degree, their perceived distress from their physical appearance or characteristics.

64. As a further example, many incarcerated persons experience depressed mood, dysphoria due to being incarcerated and away from family/loved ones, and/or anxiety, insomnia, and other DSM-5-TR recognized disorders. Research indicates that therapeutic massage may provide a benefit to patients with such conditions by improving their mood or alleviating distress. Under the formulation of "medically necessity" advanced by the Plaintiff and her expert, massages for incarcerated persons that have anxiety, insomnia, or other conditions, would be medically necessary.

65. There are interventions that are clearly and unquestionably "medically necessary." For example, if a patient presents with acute and severe (or recurrent) abdominal pain, this could implicate a number of underlying causes such as acute appendicitis, diverticulitis, abdominal obstruction, strangulated or diseased bowel, bowel perforation, acute peritonitis, ulcerative colitis, and more, all of which could have a variety of causes (e.g., bacterial infection, gunshot wound, stabbing, etc.). Given this presentation, further emergency evaluation would be medically necessary to determine if observation, and perhaps hospitalization or surgery is required. This intervention is an obvious example of medically necessity because to not intervene would impose a known high risk of morbidity/mortality, scarring, and death.

66. Other examples might include a scenario where some skin mass or growth, of unclear etiology, is identified. In that instance, diagnostic imaging and biopsy is medically necessary so as to determine whether the growth is benign or malignant, and to guide additional interventions.

67. Similarly, as we have experienced during the COVID-19 pandemic, should an individual present with acute respiratory distress, shortness of breath, and other symptoms suggestive of a COVID infection, an emergency department evaluation would be medically necessary to determine whether admission to an intensive care unit because the patient may require intubation and mechanical ventilation, and IV medications and other treatments and failure to proceed in this manner could lead to respiratory distress, hypoxia (lack of oxygen), and death. These are just some examples of procedures and interventions that can be more appropriately considered "medically necessary."

68. Thus, it is my opinion that Plaintiff and Dr. Ettner's formulation of "medically necessity" is not accurate nor practical because it is not based on an understanding of the phrase that comports with my work, education, and direct clinical and administrative experience in correctional medicine and correctional psychiatry/mental health in particular, and creates an unworkable standard in the correctional context.

Conclusions

69. For the reasons stated above, and based on my years of education, professional experience, reading and additional ongoing study and continuing medical education, it is my professional opinion that based on the available literature, reasonable medical and mental health professionals can disagree as to the medical necessity of gender-affirming surgery to treat gender dysphoria, especially in the correctional setting.

70. Accordingly, it is my opinion that the Department's decision to not approve the Plaintiff's request for a vulvoplasty in April 2022 was a reasonable decision. This opinion is based on my conclusion that there is no research on this issue in the correctional setting and the relevant research that does exist indicates problematic and conflicting findings. Thus, I conclude that there is no current or established consensus on the effectiveness of such an invasive and irreversible intervention, especially in the correctional context. Additionally, it is my opinion that an accurate and comprehensive assessment of medical necessity must allow for the consideration of factors far beyond the potential for therapeutic benefit, as opined by Dr. Ettner. Therefore, it is my opinion that the Department's determination that the vulvoplasty was not medically necessary as of April 2022, was a reasonable determination.

71. In sum, it is my opinion, that the Plaintiff has received extensive and adequate treatment of her gender dysphoria and that the Department's conclusion—that that although the Plaintiff has clearly communicated a desire for gender-affirming surgery, there is insufficient medical evidence to indicate that such a complex and irreversible surgical intervention is medically necessary at the present time—was reasonable and supported by the current body of existing empirical medical research.

THIS SPACE IS INTENTIONALLY LEFT BLANK

SIGNATURE PAGE TO FOLLOW

Pursuant to 28 U.S.C.§ 1746, I declare that the foregoing is true and correct.

This the 19th day of July, 2022.

Joseph V. Penn, MD, CCHP FAPA